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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,388	09/27/2004	Jack Auzerie	0540-1025	5049
466	7590	03/16/2006	EXAMINER	
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			EBRAHIM, NABILA G	
			ART UNIT	PAPER NUMBER
			1618	
DATE MAILED: 03/16/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/509,388

**Applicant(s)**

AUZERIE, JACK

**Examiner**

Nabila G. Ebrahim

**Art Unit**

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/27/04.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

Receipt is acknowledged of the IDS filed 9/27/04.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3, and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaw et al. US 4851392 (hereinafter "Shaw").

Shaw discloses a composition made of fiber or drug material, which is combined, with the hydrocolloid materials to form aggregates. Shaw uses different categories of drugs for his invention including, ion exchange resins such as colestyramine (col. 4, line 58), a buffer like sodium citrate and citric acid (col.7, line 61 bridging to col.8, line 1). The target pH adjustment is in a specified range of about 3.2 to about 4.7, this range overlaps with the given range in the instant application of 4-8. The composition can be made into pharmaceutical preparations like gels (col. 6, lines 64, and 65).

Note that the intended use of the claimed composition has not been given patentable weight, because the prior art compositions would be at least capable of performing said use.

**Conclusion:** claims 1-3, and 5-7 are anticipated by Shawn.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Krone et al. US 6036948 (hereinafter "Krone").

Krone discloses polyaspartamide derivatives as adsorbents for bile acids. For the "resins" being used as pharmaceuticals, colestyramine is used (col. 1,

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line 54-56), Krone also used natural amino acids like: L-alanine, L-leucine (col. 4, line 21), the instant application recites alanine and leucine, however, alanine and leucine encompasses the racemic forms of the two amino acids, which are L- and D- alanine and leucine. Krone uses also phosphate buffer (col. 6, line 30).

**Conclusion:** claim 1 is anticipated by Krone.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaw et al. US 4851392 in view of Castillo et al. WO 01/21209 (hereinafter "Castillo").

Shaw has been explained above.

Castillo teaches fatty acid/amino acid soaps, which comprise cationic exchange resins (page 5, lines 2, and 3), with buffers and pH-adjusting agents (page 7, lines 11, and 12), the pH is adjusted to 6.0 (example 2).

Accordingly, it would have been obvious to one skilled man in the art to advance the composition disclosed by Shaw and adjust the pH as Castillo teaches to about 6.0 since Castillo is disclosing an ophthalmic preparation, which is a topical preparation. The expected result would be a topical preparation containing colestyramine, a buffer and a pH regulator.

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***Correspondence***

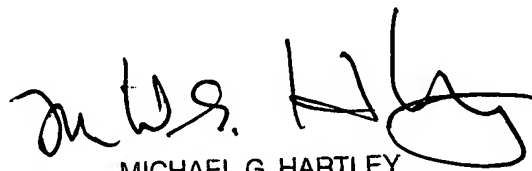
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nabila Ebrahim

3/7/06

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER